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PAK, YONG D				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/664,341

Applicant(s)

ZDANOVSKY ET AL.

Examiner

Yong D. Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-46 is/are pending in the application.
- 4a) Of the above claim(s) 12-14, 21-23, 26-29, 33, 38-40, 45 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 15-20, 25, 30-32, 34-37, and 41-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-848)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 22, 2008 has been entered.

The after final amendment filed on April 17, 2008, amending claims 1-2 and 20 and canceling claim 47, has been entered.

Claims 1-23 and 25-46 are pending. Claims 12-14, 21-23, 26-29, 33, 38-40 and 45-46 are withdrawn. Claims 1-11, 15-20, 25, 30-32, 34-37, and 41-44 are under consideration.

Response to Arguments

Applicant's amendment and arguments filed on April 17, 2008, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

Claim 17 is objected to because the claims drawn to non-elected subject matter, SEQ ID NOs:47, 48, 49, 66, 69-71 and 73-80.

Claim Rejections - 35 USC § 112-2nd paragraph

Claim 1 and claims 4-11, 17-19, 25, 30-31, 35-37, and 41-44 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the term “complementing”. The metes and bounds of this term in the context of the above claims are not clear to the Examiner. It is unclear to the Examiner what applicants mean by the above term. A perusal of the specification did not provide the Examiner with a specific definition for the above term. Therefore, it is not clear to the Examiner either from the specification or from the claim as to what characteristics of two protein destabilization sequences are “complementing”. Examiner requests clarification of the above term.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In view of the cancellation of claim 47, the rejection of claim 47 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, has been **withdrawn**.

Claims 1-11, 15-16, 18-20, 25, 30-32, 34-37, and 41-44 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-11, 15-16, 18-20, 25, 30-32, 34-37, and 41-44 are drawn to a polynucleotide encoding a fusion polypeptide comprising A) a reporter protein or a luciferase and B) at least one or two heterologous protein, such as a PEST sequence or a CL protein of SEQ ID NO:89-98, and/or one or more mRNA destabilization sequence, wherein said fusion polypeptide has a reduced half-life relative to a corresponding reporter protein which lacks the heterologous protein/mRNA destabilization sequences. The claims encompass polynucleotide encoding a fusion polypeptide comprising A) any or all reporter protein or a luciferase and one or more of B) any or all heterologous protein and/or mRNA destabilization sequence, including any or all variants, mutants and recombinants thereof, any or all PEST sequence, including any or all variants,

mutants and recombinants thereof and/or CL protein sequences of SEQ ID NO:89-98. Therefore, the claims are drawn to a polynucleotide encoding a fusion polypeptide having any structure.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, (or) chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

The recitation of "protein destabilization sequence", "mRNA destabilization sequence", "luciferase", and "reporter protein" fails to provide a sufficient description of the claimed genus of proteins as it merely describes the functional features of the genus

without providing any definition of the structural features of the species within the genus. The CAFC in *UC California v. Eli Lilly*, (43 USPQ2d 1398) stated that: "in claims to genetic material, however a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus." Similarly with the claimed genus of "protein destabilization sequence", "mRNA destabilization sequence", "luciferase", and "reporter protein", the functional definition of the genus does not provide any structural information commonly possessed by members of the genus which distinguish the protein species within the genus from other proteins such that one can visualize or recognize the identity of the members of the genus.

The specification only describes the polynucleotide having the nucleic acid sequence of SEQ ID NO:72, which encodes a fusion polypeptide comprising a specific luciferase isolated from firefly and a specific PEST sequence, a specific CL1. This is not enough and does not constitute a representative number of species to describe polynucleotides encoding a fusion polypeptide comprising a whole genus of variants, recombinant and mutants of any or all reporter protein or luciferase and any or all protein and/or mRNA destabilization sequence or any or all PEST sequences and there

is no evidence on the record of the relationship between the structure of the polynucleotide of SEQ ID NO:72 and the structure of a polynucleotide encoding a fusion polypeptide comprising any or all recombinant, variant and mutant reporter protein, protein and/or mRNA destabilization sequence or PEST sequences. Therefore, the specification fails to describe a representative species of the genus comprising polynucleotides encoding fusion polypeptides having any structure.

Given this lack of additional representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In response to the previous Office Action, applicants have traversed the above rejection.

Applicants argue that the documents submitted with the Amendment filed on March 29, 2007 as well as the references cited against the claims under 35 USC 103(a) clearly provides evidence that sequences for reporter proteins, protein destabilization sequences and mRNA destabilization sequences were known to the art and applicant need not describe what is known to the art. Examiner respectfully disagrees. As discussed in the previous Office Action (mailed on January 23, 2008), the claims are not limited to only those sequences exemplified in the specification (as detained on page 9

of the Remarks) and known sequences, but the claims encompass polynucleotide encoding a fusion polypeptide comprising A) any or all reporter protein or a luciferase, including any or all variants, mutants and recombinants thereof, and one or more of B) any or all heterologous protein and/or mRNA destabilization sequence, including any or all variants, mutants and recombinants thereof, any or all PEST sequence, including any or all variants, mutants and recombinants thereof. Therefore, the claims are drawn to a polynucleotide encoding a fusion polypeptide having widely varying structure. In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, (or) chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. Further, the

recitation of having luciferase, protein destabilization sequence, mRNA destabilization sequence or PEST sequence "property" fails to provide a sufficient description of the claimed genus of proteins as it merely describes the functional features of the genus without providing any definition of the structural features of the species within the genus. The CAFC in *UC California v. Eli Lilly*, (43 USPQ2d 1398) stated that: "in claims to genetic material, however a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. Similarly with the claimed genus of "luciferase", "protein destabilization sequence", "mRNA destabilization sequence" or "PEST sequence", the functional definition of the genus does not provide any structural information commonly possessed by members of the genus which distinguish the protein species within the genus from other proteins such that one can visualize or recognize the identity of the members of the genus.

Hence the rejection is maintained.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11, 15-20, 25, 30-32, 34-37, and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lederc et al., Corish et al., Gilon et al. and Kastelic et al.

Claims 1-11, 15-20, 25, 30-32, 34-37, and 41-44 are drawn to (A) a polynucleotide having the nucleic acid sequence of SEQ ID NO:72 which comprises a polynucleotide encoding luciferase isolated from firefly, two protein destabilizing sequence, CL1 sequence of SEQ ID NO:89 (ACKNWFSSLSHFVIHL) and a PEST sequence or (B) a polynucleotide encoding a fusion protein comprising a reporter

protein and one or two protein destabilizing sequence or mRNA destabilization sequence and further comprising an inducible promoter and a vector and host cell comprising said polynucleotide, wherein the half life of expression of luciferase is 20 or 30 minutes.

Leclerc et al. (form PTO-1449) discloses polynucleotide encoding a luciferase isolated from firefly and a PEST sequence obtained from the C-terminal fragment mODC, further comprising an inducible promoter and a vector and host cell comprising said polynucleotide, wherein the half life activity of luciferase is decreased (page 590). The luciferase of the instant invention and the luciferase of Leclerc et al. are identical because both are isolated from the same source, firefly. The PEST sequence of Leclerc et al. is 100% identical to the PEST sequence used by the instant invention (See Figure 1 on page 594 and page 31 of the instant specification). Leclerc et al. discloses that when using luciferase as reporter proteins, owing to the accumulation of residual luciferase (3-4 hour half-life of firefly luciferase), the rapid increase or decreases in gene expression may not be detected (abstract) and that destabilized luciferases having a shorter half-life is advantageous in better quantifying gene expression (pages 590 and 600).

The difference between the reference of Leclerc et al. and the instant invention is that Leclerc et al. does not teach a polynucleotide encoding a fusion protein comprising two protein destabilizing sequences, such as a CL1 sequence, wherein the half life expression of luciferase is 20 or 30 minutes, or a polynucleotide comprising a mRNA destabilizing sequence.

Corish et al. (Protein Eng. 1999 Dec;12(12):1035-40 - form PTO-1449) discloses a polynucleotide encoding a fusion protein comprising a reporter protein and two protein destabilizing sequences, a PEST sequence and a cyclin destruction box (page 1035, right column and Figure 1 on page 1036). Corish et al. discloses that the combination of two protein destabilization sequences produced a reporter protein having decreased half life as compared to the reporter protein having one of the protein destabilizing sequences (abstract). Corish et al. discloses that the half-life of luciferase is much shorter than GFP. With this teaching at hand, one having skill in the art would have recognized the advantage to further decrease the half-life of the luciferase of Leclerc et al. by using an additional destabilizing sequences in conjunction with the PEST sequence, such as the cyclin destruction box of Corish et al. or other protein destabilizing sequences known in the art, such as CL proteins, or other methods that decrease expression of proteins, in order to make a reporter protein with a short half life of expression.

Gilon et al. (form PTO-1449) discloses several protein destabilizing sequence, such as a CL1 sequence (ACKNWFSSLSHFVIHL), which is attached C-terminal to the protein of interest and which is 100% identical to the CL1 sequence of SEQ ID NO:89 (ACKNWFSSLSHFVIHL) (See Table 1 on page 2763 of Gilon et al. and on page 31 of the instant specification).

Kastelic et al. (WO 00/39314 – form PTO-1449) discloses mRNA destabilizing sequences that limit expression of genes of interest (pages 1 and 3) and polynucleotide comprising a reporter DNA and a mRNA destabilizing sequences (page 3). With this

teaching at hand, one having skill in the art would have recognized to destabilize luciferase by using one or more protein destabilizing sequences and/or one or more mRNA destabilizing sequences.

Therefore, in combining the teachings of Leclerc et al., Corish et al., Gilon et al. and Kastelic et al., it would have been obvious to one having ordinary skill in the art to make a polynucleotide encoding a fusion protein comprising a firefly luciferase and one or more protein destabilization sequences, such as a PEST sequence and a CL1 sequence C-terminal to the luciferase, and/or one or more mRNA destabilization sequence. One of ordinary skill in the art would have been motivated to use other protein destabilizing sequences such as the CL sequences of Gilon et al. or a cyclin destruction box sequence as taught by Corish et al. or one or more mRNA destabilization sequences of Kastelic et al. in conjunction with a PEST sequence in order to further reduce the half life activity/expression of luciferase. One of ordinary skill in the art would have had a reasonable expectation of success since Leclerc et al. teaches reducing the half-life activity of a luciferase by using a PEST sequence, Corish et al. teaches that a combination of two protein destabilization sequences protein destabilizing sequences decreases half-life of reporter protein more than using only one of the protein destabilizing sequence, Gilon et al. teaches CL protein destabilizing sequences that can be used to destabilize proteins and Kastelic et al. teaches destabilizing reporter proteins using mRNA destabilizing sequences.

Therefore, the above references render claims 1-11, 15-20, 25, 30-32, 34-37, and 41-44 *prima facie* obvious to one of ordinary skill in the art.

In response to the previous Office Action, applicants have traversed the above rejection.

Applicants argue one of skill in the art would not look to combining different types of destabilization sequences because the half-life of the fusion protein in Corish et al. is almost exclusively the result of the presence of the CDB sequence and there was little benefit in Corish et al. to the presence of a different protein destabilization sequence in decreasing protein half-life. Examiner respectfully disagrees. Corish et al. disclose that the GFP alone has a half-life of 26 h (page 1037, 2nd paragraph under "Results"), the GFP-PEST fusion protein has a half-life of 9.8 h (page 1037, 2nd paragraph under "Results"), the GFP-CDB fusion has a half-life of 5.8 h (page 1037, 4th paragraph under "Results") and that the GFP-CDB-PEST fusion protein has a half-life of 5.5 h. Therefore, the presence of two different protein destabilization sequences (PEST and CDB) has an additive effect. Thus, one of ordinary skill in the art would have been motivated to use other protein destabilizing sequences such as the CL sequences of Gilon et al. or a cyclin destruction box sequence as taught by Corish et al. or one or more mRNA destabilization sequences of Kastelic et al. in conjunction with a PEST sequence in order to further reduce the half life activity/expression of luciferase.

Applicants also argue that prior to applicant's disclosure, it was unknown whether different protein destabilization sequences could have complementing effects. Examiner respectfully disagrees. First, it is not quite clear what applicants mean by the phrase "complementing effects". Second, contrary to applicant's argument, Corish et al. does teach that use of two protein destabilizing sequences further decreases the protein

half-life than when one protein destabilizing sequence is used. Corish et al. disclose that the GFP alone has a half-life of 26 h (page 1037, 2nd paragraph under "Results"), the GFP-PEST fusion protein has a half-life of 9.8 h (page 1037, 2nd paragraph under "Results"), the GFP-CDB fusion has a half-life of 5.8 h (page 1037, 4th paragraph under "Results") and that the GFP-CDB-PEST fusion protein has a half-life of 5.5 h. Therefore, the fusion protein GFP-CDB-PEST of Corish et al. has a reduced half-life relative to the GFP protein lacking any destabilizing sequences and said fusion protein has a further reduced half-life compared GFP protein having only one of the destabilizing sequences (GFP-CDB fusion and GFP-PEST fusion).

Applicants argue that one of skill in the art would not consider combining RNA and protein destabilization sequences with a reporter gene since reduction in available reporter protein mRNA transcripts that can be translated in conjunction with a reduction in reporter protein half-life may not yield sufficient reporter protein for any particular assay. Examiner respectfully disagrees. Leclerc et al. discloses that when using luciferase as reporter proteins, owing to the accumulation of residual luciferase (3-4 hour half-life of firefly luciferase), the rapid increase or decreases in gene expression may not be detected (abstract) and that destabilized luciferases having a shorter half-life is advantageous in better quantifying gene expression (pages 590 and 600). With this teaching at hand, one having skill in the art would have recognized the advantage to decreasing the accumulation of luciferase of Leclerc et al. by using techniques available in the art, by using protein destabilizing sequences or mRNA destabilizing sequences. Since Corish et al. discloses that using two protein destabilizing sequences

instead of one further reduces the half-life the GFP protein and Kastelic et al. discloses that mRNA destabilizing sequences that limit expression of genes of interest (which destabilizes transcription), one having skill in the art would have been motivated to also use more than one type of protein or mRNA destabilizing sequences for compounding the effect of destabilizing sequences on the half-life of luciferase. One of ordinary skill in the art would have had a reasonable expectation of success since Leclerc et al. teaches reducing the half-life activity of a luciferase by using a PEST sequence, Corish et al. teaches that a combination of two protein destabilization sequences protein destabilizing sequences decreases half-life of reporter protein more than using only one of the protein destabilizing sequence, Gilon et al. teaches CL protein destabilizing sequences that can be used to destabilize proteins and Kastelic et al. teaches destabilizing reporter proteins using mRNA destabilizing sequences.

Hence the rejection is maintained.

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Yong D Pak/

Primary Examiner, Art Unit 1652